

AMENDMENTS TO SPECIFICATION

(Version with markings to show changes made)

ABSTRACT

[0379] This invention relates to crystals of whole antibodies and fragments thereof, and formulations and compositions comprising such crystals. More particularly, methods are provided for the crystallization of high concentrations of whole antibodies, and fragments thereof, in large batches, and for the preparation of stabilized whole antibody crystals for use alone, or in dry or slurry formulations or compositions. This invention also relates to methods for stabilization, storage and delivery of biologically active whole antibody crystals.

[0380] The present invention further relates to methods using whole antibody crystals, antibody fragment crystals, or compositions or formulations comprising such crystals for biomedical applications, including biological delivery to humans and animals. More particularly, [highly concentrated whole antibody or antibody fragment crystal formulations or compositions are useful for delivery of large amounts of antibodies in a small volume to a subject, when and where they are needed. According to one embodiment of this invention,] whole antibody crystals or antibody fragment crystals, or crystal compositions or formulations thereof, are used as a carrier-free delivery system which can slowly release active whole antibodies or fragments thereof, to a subject, where and when they are needed. [According to an alternate embodiment of this invention, whole antibody crystals or antibody fragment crystals, or crystal formulations thereof, are encapsulated

within a matrix comprising a polymeric carrier to form a composition.

Methods are also provided for preparing stabilized formulations of whole antibody crystals or antibody fragment crystals using pharmaceutical ingredients or excipients and optionally encapsulating the crystals or crystal formulations in a polymeric carrier to produce compositions and using such protein crystals for biomedical applications, including delivery of therapeutic proteins and vaccines.]